

CLAIMS:

1. A catheter assembly comprising:
 - a catheter, the catheter comprising a catheter shaft;
 - a first rotatable sheath, the first rotatable sheath being disposed about a

5 portion of the catheter shaft, the first rotatable sheath having a length substantially less than that of the catheter shaft, the first rotatable sheath being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first sheath being rotatable about the portion of the catheter shaft;
 - a first guidewire housing, the first guidewire housing defining a first

10 guidewire lumen for passage of a first guidewire therethrough, at least a portion of the first guidewire housing being engaged to the first rotatable sheath;
 - a first stent, the first stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the stent being disposed about at least a portion of the first rotatable sheath; and
 - 15 a second stent, the second stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the second stent being adjacent to the first stent.
2. The catheter assembly of claim 1 wherein the portion of the catheter shaft comprises a balloon.
- 20 3. The catheter assembly of claim 2 wherein when the second stent is in the reduced stent state the second stent is disposed about the catheter shaft longitudinally adjacent to the first rotatable sheath.
4. The catheter assembly of claim 1 wherein when the second stent is in the reduced stent state the second stent is disposed about the catheter shaft longitudinally adjacent to the

25 first rotatable sheath.
5. The catheter assembly of claim 1 wherein when the second stent is in the reduced stent state the second stent is positioned longitudinally adjacent to the first stent along the first rotatable sheath.

6. The catheter assembly of claim 2 wherein when the second stent is in the reduced stent state the second stent is positioned longitudinally adjacent to the first stent along the first rotatable sheath.
7. The catheter assembly of claim 1 wherein when the first stent is in the reduced stent state at least a portion of the first stent overlays at least a portion of the first guidewire housing.
8. The catheter assembly of claim 7 wherein when the first stent is in the reduced stent state at least a distal portion of the first guidewire housing extends externally from the first stent to a position between the first stent and the second stent.
9. The catheter assembly of claim 8 wherein the second stent comprises a distal end region, a proximal end region and a body region therebetween, in the reduced stent state at least the proximal end region having a diameter less than that of the body region.
10. The catheter assembly of claim 8 wherein the diameter of at least the proximal end region tapers from the body region.
11. The catheter assembly of claim 1 further comprising a second rotatable sheath, the second rotatable sheath being disposed about a portion of the catheter shaft longitudinally adjacent the first rotatable sheath, the second rotatable sheath being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the second sheath being rotatable about the portion of the catheter shaft longitudinally adjacent the first rotatable sheath, the second rotatable sheath having a length substantially less than that of the catheter shaft; and
 a second guidewire housing, the second guidewire housing defining a second guidewire lumen for passage of a second guidewire therethrough, at least a portion of the second guidewire housing being engaged to the second rotatable sheath.
12. The catheter assembly of claim 11 wherein the portion of the catheter shaft comprises a first balloon and the portion of the catheter longitudinally adjacent the first rotatable sheath comprises a second balloon.
13. The catheter assembly of claim 1 further comprising a second rotatable sheath, when the first stent is in the reduced stent state the second rotatable sheath is rotatably disposed

about at least a portion of the first stent, in the reduced stent state the second stent is disposed about the second rotatable sheath.

14. The catheter assembly of claim 13 wherein the second rotatable sheath is bio-absorbable.
- 5 15. The catheter assembly of claim 13 wherein the second rotatable sheath is retractable from about the first stent.
16. The catheter assembly of claim 13 wherein the second rotatable sheath is expandable from a reduced sheath state to an expanded sheath state.
17. The catheter assembly of claim 1 wherein the first stent is selected from at least one
10 member of the group consisting of: a self-expanding stent, a balloon-expandable stent, a hybrid expandable stent and any combination thereof.
18. The catheter assembly of claim 1 wherein the second stent is selected from at least one member of the group consisting of: a self-expanding stent, a balloon-expandable stent, a hybrid expandable stent and any combination thereof.
- 15 19. The catheter assembly of claim 13 wherein at least a portion of at least one member of the group consisting of the first stent, the second stent, the first rotatable sheath, the second rotatable sheath, and any combination thereof is coated with at least one therapeutic agent.
20. The catheter assembly of claim 1 wherein at least a portion of at least one member
20 of the group consisting of the first stent, the second stent, the first rotatable sheath and any combination thereof is coated with at least one therapeutic agent.
21. The catheter assembly of claim 20 wherein the at least one therapeutic agent is at least one non-genetic therapeutic agent selected from at least one member of the group consisting of: anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and
25 PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine; antineoplastic/antiproliferative/anti-miotic agents such as paclitaxel, 5-
30 fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and

thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; anti-coagulants such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides; vascular cell growth promoters such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters, vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms, and any combinations thereof.

22. The catheter assembly of claim 20 wherein the at least one therapeutic agent is at least one genetic therapeutic agent selected from at least one member of the group consisting of: anti-sense DNA and RNA; DNA coding for anti-sense RNA, tRNA or rRNA to replace defective or deficient endogenous molecules; angiogenic factors including growth factors such as acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor and insulin like growth factor; cell cycle inhibitors including CD inhibitors, thymidine kinase ("TK") and other agents useful for interfering with cell proliferation; at least one of the family of bone morphogenic proteins ("BMP's") such as BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7; dimeric proteins such as homodimers, heterodimers, or combinations thereof, alone or together with other molecules; molecules capable of inducing an upstream or downstream effect of a BMP such as "hedgehog" proteins, or the DNA's encoding them and any combinations thereof.

23. The catheter assembly of claim 20 wherein the at least one therapeutic agent is at

least one type of cellular material selected from at least one member of the group consisting of: cells of human origin (autologous or allogeneic); cells of non-human origin (xenogeneic) and any combination thereof.

24. The catheter assembly of claim 23 wherein the cellular material is selected from at
 5 least one member of the group consisting of: side population cells; lineage negative cells; lineage negative CD34⁻ cells; lineage negative CD34⁺ cells; lineage negative cKit⁺ cells; mesenchymal stem cells; cord blood cells; cardiac or other tissue derived stem cells; whole bone marrow; bone marrow mononuclear cells; endothelial progenitor cells; satellite cells; muscle derived cells; go cells; endothelial cells; adult cardiomyocytes; fibroblasts; smooth
 10 muscle cells; cultures of mesenchymal stem cells with 5-aza forces differentiation into cardiomyocytes; adult cardiac fibroblasts + 5-aza; genetically modified cells; tissue engineered grafts; MyoD scar fibroblasts; Pacing cells; embryonic stem cell clones; embryonic stem cells; fetal or neonatal cells; immunologically masked cells; tissue engineered grafts; genetically modified cells; teratoma derived cells and any combinations
 15 thereof.

25. The catheter assembly of claim 20 wherein the at least one therapeutic agent comprises at least one polymer coating, the at least one coating selected from at least one member of the group consisting of: polycarboxylic acids; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; polyvinylpyrrolidone; cross-linked
 20 polyvinylpyrrolidone; polyanhydrides including maleic anhydride polymers; polyamides; polyvinyl alcohols; copolymers of vinyl monomers such as EVA; polyvinyl ethers; polyvinyl aromatics; polyethylene oxides; glycosaminoglycans; polysaccharides; polyesters including polyethylene terephthalate; polyacrylamides; polyethers; polyether sulfone; polycarbonate; polyalkylenes including polypropylene, polyethylene and high molecular
 25 weight polyethylene; halogenated polyalkylenes including polytetrafluoroethylene; polyurethanes; polyorthoesters; proteins; polypeptides; silicones; siloxane polymers; polylactic acid; polyglycolic acid; polycaprolactone; polyhydroxybutyrate valerate and blends and copolymers thereof; coatings from polymer dispersions such as polyurethane dispersions (BAYHDROL[®], etc.), fibrin, collagen and derivatives thereof; polysaccharides
 30 such as celluloses, starches, dextrans, alginates and derivatives; hyaluronic acid; squalene

- emulsions; polyacrylic acid, a copolymer of polylactic acid and polycaprolactone; medical-grade biodegradable materials such as PGA-TMC, Tyrosine-Derived Polycarbonates and arylates; polycaprolactone co butyl acrylate and other co polymers; Poly-L-lactic acid blends with DL-Lactic Acid; Poly(lactic acid-co-glycolic acid); polycaprolactone co PLA;
- 5 polycaprolactone co butyl acrylate and other copolymers; Tyrosine-Derived Polycarbonates and arylate; poly amino acid; polyphosphazenes; polyiminocarbonates; polydimethyltrimethylcarbonates; biodegradable CA/PO₄'s; cyanoacrylate; 50/50 DLPLG; polydioxanone; polypropylene fumarate; polydepsipeptides; macromolecules such as chitosan and Hydroxylpropylmethylcellulose; surface erodible material; maleic anhydride
- 10 copolymers; zinc-calcium phosphate; amorphous polyanhydrides; sugar; carbohydrate; gelatin; biodegradable polymers; and polymers dissolvable in bodily fluids; A block copolymers; B block copolymers and any combinations thereof.
26. The catheter assembly of claim 1 further comprising a lubricious coating, the lubricious coating positioned between at least a portion of the first rotatable sheath and the
- 15 a portion of the catheter shaft.
27. The catheter assembly of claim 1 wherein the first rotatable sheath is at least partially constructed from a hydrophilic polymer material.
28. The catheter assembly of claim 1 wherein the first rotatable sheath is at least partially constructed from a tecophilic material.
- 20 29. The catheter assembly of claim 1 wherein the first rotatable sheath is at least partially constructed from a first material and a second material.
30. The catheter assembly of claim 1 wherein the first rotatable sheath is at least partially constructed from at least one material of the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes,
- 25 engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene, polyamide, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.

31. The catheter assembly of claim 29 wherein the first material is a polymer matrix and the second material is at least one distinct member of reinforcing material at least partially supported within the polymer matrix.
32. The catheter assembly of claim 31 wherein polymer matrix is selected from at least
 5 one material from the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene and any combination thereof.
33. The catheter assembly of claim 31 wherein the reinforcing material is selected from
 10 at least one material of the group consisting of polyamide, polyethylene, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.
34. A method of treating a vessel bifurcation comprising the steps of:
- advancing a portion of a catheter assembly along a first guidewire to a vessel
 15 bifurcation, the catheter assembly comprising:
 - a catheter, the catheter comprising a catheter shaft;
 - a first rotatable sheath, the first rotatable sheath being
 disposed about a portion of the catheter shaft, the first rotatable sheath having a length
 substantially less than that of the catheter shaft, the first rotatable sheath being expandable
 20 from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first
 sheath being rotatable about the portion of the catheter shaft;
 - a first guidewire housing, the first guidewire housing defining
 a first guidewire lumen for passage of the first guidewire therethrough, at least a portion of
 the first guidewire housing being engaged to the first rotatable sheath;
 - 25 a first stent, the first stent being expandable from a reduced
 stent state to an expanded stent state, in the reduced stent state the stent being disposed
 about at least a portion of the first rotatable sheath; and
 - a second stent, the second stent being expandable from a
 reduced stent state to an expanded stent state, in the reduced stent state the second stent
 30 being adjacent to the first stent;

- allowing the rotatable sheath to align the first stent with a first branch of the vessel bifurcation;

- deploying the first stent to the expanded stent state within the vessel adjacent to the first branch of the bifurcation;

5 - deploying the second stent to the expanded stent state within a second branch of the bifurcation; and

- withdrawing the catheter assembly from the vessel.

35. The method of claim 34 further comprising the steps of:

10 - advancing a portion of a second catheter assembly along the first guidewire to the vessel bifurcation, the second catheter assembly having a third stent mounted thereon, the third stent being expandable from a reduced stent state to an expanded stent;

15 - deploying the third stent to the expanded stent state within the vessel wherein a first portion of the third stent is positioned between the first stent and the second stent and a second portion of the third stent is positioned within the first branch of the bifurcation.

36. A method of treating a vessel bifurcation comprising the steps of:

20 - advancing a primary guidewire and a secondary guidewire through a vessel to a bifurcation, the primary guidewire extending from the vessel into a primary branch of the bifurcation, the secondary guidewire extending from the vessel into a secondary branch of the bifurcation;

 - advancing a portion of a first catheter assembly along the primary guidewire and the secondary guidewire to the vessel bifurcation, the first catheter assembly comprising:

25 a first catheter, the first catheter comprising a first catheter shaft the first catheter shaft defining a primary guidewire lumen for passage of the primary guidewire therethrough;

 a first rotatable sheath, the first rotatable sheath being disposed about a portion of the catheter shaft, the first rotatable sheath having a length substantially less than that of the catheter shaft, the first rotatable sheath being expandable

from a reduced sheath state to an expanded sheath state, in the reduced sheath state the first rotatable sheath being rotatable about the portion of the first catheter shaft;

a secondary guidewire housing, the secondary guidewire housing defining a secondary guidewire lumen for passage of the secondary guidewire therethrough, at least a portion of the secondary guidewire housing being engaged to the first rotatable sheath; and

a first stent, the first stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the first stent being disposed about at least a portion of the first rotatable sheath, at least a portion of the secondary guidewire housing positioned between the first rotatable sheath and the first stent, wherein a portion of the secondary guidewire housing extends radially through a secondary opening in the first stent;

- allowing the first rotatable sheath to align the first stent with the secondary branch of the vessel bifurcation;
- deploying the first stent to the expanded stent state, wherein a proximal portion of the first stent is positioned within the vessel proximally adjacent to the bifurcation, a distal portion of the first stent is positioned in the primary branch of the bifurcation and the secondary opening of the first stent is in fluid communication with the secondary branch of the bifurcation; and

- withdrawing the catheter assembly from the vessel.

37. The method of claim 36 further comprising the steps of

- advancing a portion of a second catheter assembly along the primary guidewire and the secondary guidewire to the vessel bifurcation, the catheter assembly comprising:

a second catheter, the second catheter comprising a second catheter shaft the second catheter shaft defining a secondary guidewire lumen for passage of the second guidewire therethrough;

a second rotatable sheath, the second rotatable sheath being disposed about a portion of the second catheter shaft, the second rotatable sheath having a length substantially less than that of the second catheter shaft, the second rotatable sheath

being expandable from a reduced sheath state to an expanded sheath state, in the reduced sheath state the second rotatable sheath being rotatable about the portion of the second catheter shaft;

5 a primary guidewire housing, the primary guidewire housing defining a primary guidewire lumen for passage of the primary guidewire therethrough, at least a portion of the primary guidewire housing being engaged to the second rotatable sheath; and

10 a second stent, the second stent being expandable from a reduced stent state to an expanded stent state, in the reduced stent state the second stent being disposed about at least a portion of the second rotatable sheath, at least a portion of the primary guidewire housing positioned between the second rotatable sheath and the second stent, wherein a portion of the primary guidewire housing extends radially through a secondary opening in the second stent;

15 - allowing the second rotatable sheath to align the second stent with a first branch of the vessel bifurcation;

- deploying the second stent to the expanded stent state, wherein a proximal portion of the second stent is positioned within the first stent and a distal portion of the second stent extends through the secondary opening of the first stent and into the secondary branch of the bifurcation, and the secondary opening of the second stent is in fluid communication with the first branch of the bifurcation; and

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- withdrawing the catheter assembly from the vessel.

38. A method of treating a vessel bifurcation comprising the steps of:

25 advancing a portion of at least one catheter to a vessel bifurcation, the at least one catheter having at least two expandable stents disposed thereabout, at least one of the stents being substantially free to rotate about a shaft of the catheter prior to expansion.

39. The method of claim 38 wherein the at least one catheter comprises a rotatable sheath, the rotatable sheath being substantially free to rotate about the shaft, prior to expansion the at least one stent being fixedly disposed about the rotatable sheath.

40. The method of claim 38 wherein the shaft comprises a balloon.